

HIMA Statement 1307 '98 SEP 11 P12:28
CBER 406(b) Meeting

Friday, August 28, 1998

Good Morning. My name is Nancy Hornbaker and I am the Director of Regulatory Affairs for Chiron Diagnostics a business of Chiron Corporation. I am here today representing the Health Industry Manufacturers Association (HIMA). HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. CBER's regulation of devices is an import issue for many of our members.

HIMA is encouraged by the Agency's efforts to gain input from the regulated industry, consumers and academia on how FDA can meet its statutory obligations under the Food, Drug and Cosmetic Act. Such a dialogue with all FDA's constituencies is very important as FDA, and in particular CBER, attempts to meet the challenges of the future.

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We appreciate the opportunity to be a part of the discussions and we will submit more extensive written comments to the docket. FDA has asked that comments address six questions. We will attempt to provide brief comments on each question.

Additional Objectives

FDAMA covers the broad range of agency activities and FDA should be complimented for attempting to determine whether there are other objectives or issues that may be added to the FDA plan. If FDA accomplishes all the objectives outlined by FDAMA in the timeframes specified by Congress, we in industry will be more than willing to look at ways to tweak the system to gain even greater efficiencies.

The one thing we might add, is a reminder that FDA's mission has been broadened. The focus is not only the protection of the public health but also promotion of the public health. This change in focus results in a delicate balancing of the risks and benefits in an environment that is essentially risk adverse. We hope that FDA will develop a reasonable approach to its revised mission that will direct future agency activities.

Improving Review Process

CBER has made significant strides toward improving its licensure processes. Replacement of the PLA and ELA with the ~~blood~~^{biologic} license application process shows great promise. We believe that improvements like this will make the licensure process more efficient and look forward to the same efforts being made to improve CBER's review and regulation of devices.

CBER's focus on products covered by the Prescription Drug User Fee Act (PDUFA) and blood and plasma establishments has left the device industry at the end of the line in terms of product reviews. As a result, some products have been under review for more than 18 months and few others for 24 months. CBER reviewers have often remarked to complaining manufacturers that their products are not covered by user fees and they must wait until the PDUFA products are reviewed. This is not the way to win friends and influence people.

We suggest the following:

- ✓ CBER should consider reallocating some of its resources to clear up the backlog of device reviews much like its sister Center, CDRH.

- ✓ To reduce the workload, harmonize device review processes (instrumentation) with CDRH review processes so that devices that can be used for blood screening or diagnosis will not require a dual review. Allow CDRH to take the lead and, where necessary, to address specific CBER concerns add review requirements.
- ✓ Make available more templates to make the submission and review processes simpler.
- ✓ Evaluate current processes to determine what things add no or little value to the process. Stop all functions with no or little pay-off.
- ✓ Publish flow charts or internal processes for all submissions so that the process is transparent.
- ✓ Finally, remember that part of promotion of the public health is getting good products to the market.

Product Quality

Product quality is important to both CBER and industry. This joint concern is often overlooked. Manufacturers have a responsibility to ensure that their products are of the highest quality possible. Their goal is to design in quality.

We believe that CBER has at its disposal an arsenal of tools to help ensure product quality. These tools include the opportunity for early and frequent meetings with industry to help design study protocols, good technical reviews and an efficient and effective compliance program. Application of the device quality systems regulations, particularly the design control provisions, to devices regulated by CBER is another important tool. CBER, to its credit has always been willing to meet with industry to discuss clinical protocols and the content of product submissions.

In light of the design control requirements, CBER should reevaluate the current requirements for lot release. The lot release program implies that manufacturers can test in quality. Efficiencies in this process may also be gained by reviewing the programs used by other countries.

Communications

On certain levels CBER's communications have improved. CBER has published a number of guidance documents and has given industry an opportunity to comment. More is needed. The device industry has not been given the opportunity for meaningful participation in the guidance development process. CDRH has already recognized that much can be

gained from early interaction between the agency and industry during the guidance development process. In fact, industry has developed the strawman for a number of guidance documents. We believe that CBER guidances could benefit from this type of collaborative effort as well.

Access to Scientific and Technical Expertise

CBER should make more use of scientific workshops to gain a broader perspective on scientific and technical issues. The current advisory committee is often perceived as a rubber stamp for CBER activities. Workshops permit an open dialogue and exchange of ideas, which is precluded by the advisory committee structure. CBER has already conducted a workshop addressing implementation of nucleic acid testing for HIV-1 for blood screening and another is planned for nucleic acid testing for hepatitis and other viruses.

We realize that workshops can be resource intensive. FDA should consider allowing industry or professional associations to sponsor the workshops where possible.

The “vendor day” program should be expanded to include products regulated by CBER. In addition, CBER reviewers should be allowed to make site visits to companies to gain a better understanding of the products regulated by CBER.

Outreach Efforts

CBER’s outreach programs for the blood community are important and should be continued. Use of the website and professional organizations provide another avenue for providing important information to the public. With regard to providing information about new products, new product promotion is not an FDA function. Notification of product approvals via the *Federal Register* or the CBER website is sufficient to provide the public notice regarding new product availability.

Closing

In closing, HIMA thanks FDA for the opportunity to provide input on these important issues. We will submit written comments to the docket. We look forward to working with CBER to improve its device review processes.